FINAL TRANSCRIPT

CCBNStreetEvents℠

Event Transcript

BPUR - Biopure`s Regulatory and Operating Plans

Event Date/Time: Oct. 30. 2003 / 11:30AM ET

FINAL TRANSCRIPT

BPUR - Biopure`s Regulatory and Operating Plans

CORPORATE PARTICIPANTS

Thomas Moore
CEO, President - Biopure Corporation

David Uchero
Senior Regulatory Manager - Biopure Corporation

CONFERENCE CALL PARTICIPANTS

Marcus Denennero (ph)
Smith Barney - Analyst

Bruce Peterson (ph)
Janney Montgomery Scott - Analyst

Gudrim Bowler (ph)
- Analyst

Unidentified Participant

Sapna Srivastava
ThinkEquity Partners - Analyst

David Hoffman
Accepitor Capital Management - analyst

Jakar Boz
Greenberg Healthcare - Analyst

Kevin Tang (ph)
Tang Capital - Analyst

Steven Marks (ph)
Blue Ridge Capital - Analyst

PRESENTATION

Operator

Good morning, my name is Corey, and I will be your conference facilitator today. At this time, I would like to welcome everyone to the Biopure Corporation Regulatory Update conference call. All lines have been placed on mute to prevent any background noise. After the speaker's remarks, there will be a Q&A period. IF you would like to ask your question during this time, please press * then 1 on your telephone keypad. If you would like to withdraw your question, press * then 2 on your telephone keypad. Thank you. Mr. Douglas, sir, you may begin your conference.

Unidentified Participant

Good morning everyone and thank you for joining us on our conference call today. We'll be discussing regulatory and operating update after which we'll answer a few questions. But before we begin, I'd like to point out that during this call we may discuss projections and other forward-looking statements which involve risks and uncertainties that could cause the company's actual results or performance to differ materially from those projected. The condensed list of these respective factors appears at the end of today's press release, which you can access on the internet, and there is a more comprehensive discussion of these risk factors on our SEC filings at Biopure.com. Now I'd like to turn over the call to our CEO and President Tom Moore.

Thomas Moore - *CEO, President - Biopure Corporation*

Good morning, everybody. I would like to add my thanks to you for joining us this morning. Around the table here I also have Ron Richards our CFO, and also on the line, David Zuchero who's mentioned on the press release this morning, who'll be introducing himself briefly a little bit later in our remarks. As you all know this morning, we announced three or four additional new events for Biopure Corporation. First of all, our financial response time to the questions that the FDA sent us on our biological license application, questions that we received in late July. Second, our engagement of David Zuchero on an interim basis as our senior regulatory manager replacing Howard Richman. And third, a reduction in force by the company to reduce our cash burn over the next several months as we repair our responses. I'm going to address each of those briefly, and then we'll throw it open to questions.

In terms of the response timing, as many of you know, we said all along that the precise time of that response would be dependent on our discussions with FDA, which we conducted during the month of September. While the discussion covered several items: specific clarifications of certain questions, the key issue vis- -vis our timing was to see whether or not we could use sampling approaches as opposed to having to collect all the blood transfusions and other source data that the FDA requested. The FDA in all these discussions was very responsive, answering all our questions promptly and we engaged in good discussion. But nevertheless the bottom line conclusion that we drew was that the FDA was not in a position where they could tell us of the sampling approach in fact would be guaranteed to meet the full needs of what they wanted to see.

On that basis, we made the decision that we're going to go out and collect all the source data we requested which unfortunately is going to be more time-consumptive that we would have originally hoped. As we then stated, there's simply as not as much data at hand for us to be able to answer these questions without going out to the various sites. So, we already have a

traveling team in place collecting the information from the various sites, but as we look at the total picture we wanted to set an expectation for the market which was recently conservative and one we could make, and by the end of June 2004 is precisely the expectation we want to set. In terms of the change in regulatory leadership, change in personnel is always difficult particularly in a somewhat high-profile position like this, so we believe that it's an opportune time for us to make this change for the company.

Howard's worked very hard the last several months in our dialogue with the FDA to define the precise scope of the data collection work we need to do, and we're very appreciative of the job he has done in that area. We're now in a position where we're sort of a regulatory law, by that I mean we know exactly what we have to do. We know what the roadmap is that the FDA has set out for us to respond to their questions, and our teams are working hard to do that. Howard is not in a position where he's managing the preparation of that response and so in a sense, there's not much to be done in this area until those responses are closer to being submitted to the FDA. At the same time, we are looking at the development of other indications which was mentioned in our press release in both cardiac e d e m a (ph) as well as some trauma, as well as exploring international opportunities. We felt as we looked at this broader range of strategic issues that this was a good time to add additional regulatory and strategic resources to our management portfolio.

So on that basis, we decided to make this change, and we are very happy to be able to secure on an interim basis the services of the Chesapeake Regulatory Group and in particular, David Zuchero to work us through this process while we're in the process of bringing in a new in-company regulatory head. And because I know there's a lot of interest in David in this hand-off, I asked David to participate in this call. I've asked David to only provide you with some perspective with his background, he's not in a position to answer any of your questions about the regulatory process and we're not going to ask him to do that. So, David, I'd appreciate it if you could briefly introduce yourself.

David Uchero - *Senior Regulatory Manager - Biopure Corporation*

Sure, thanks a lot Tom. My name is David Zuchero. I'm basically a 25 year veteran in the biopharmaceutical industry, the last 13 years of which I have founded and headed the Chesapeake Regulatory Group, CRG. CRG basically provides high-level strategic regulatory planning and regulatory liason services so we help companies figure out where they're going with their products and how to get to FDA approval. We manage and coordinate the development approval process with the FDA. We've worked with some of the largest companies as well as intermediate and start-up companies. We've probably worked on close to 50 approved products both in biologics and drugs. Basically I know personally I've worked on blood-replacement products in the past and am excited about helping Biopure move this product forward to approval.

I think that's about it for me.

Thomas Moore - *CEO, President - Biopure Corporation*

Thank you David. Again, at the risk of frustrating some on the call, that's all we're going to ask David to say. While he has spent time working with us on this, he's not in a position as yet to comment on our regulatory situation. So unfortunately you're just going to have to rely on me for that. David, thank you very much.

The third item we addressed in our... I'll go back a little bit, as some will ask "Well, how do we and the CRG come together?" As many of you know, we're very fortunate to have on our board, folks with extensive FDA experience notably Richard Crout who was division chief for the FDA as well as a variety of other consultants and advisors that David C a i n e (ph) highly recommended, and so we're very pleased to be able to bring him onto the team.

The third matter we talked about in our release today was our reduction in force, which is the polite way to describe the lay-offs that we've in fact already executed this morning. Ever since I joined this company, investors have been coaching me on the need to reduce our basic burn rate with the company. In the process, in September and in earlier October when we got a real handle on the collecting timing of our response, giving the time it's going to take to collect this source information. It seemed right to finally make the step to reduce that burn rate, as painful as that is both for this company and for me personally.

Fundamentally, this is a manufacturing reduction in force. We've been staffing our facility to have a capacity of 50,000 units per year. Until we get FDA approval, that's simply not a likely demand situation, and so we have in essence reduced our manufacturing staffing which will enable us to have an annual capacity of 10,000 units a year, which is certainly adequate for our needs on our growing Oxyglobin business as well as Hemopure. The way we've approached this is to decide to keep

the manufacturing facility running basically all the time, and in a position where we can ramp it back up to full capacity with minimum effort and with no need to requalify or revalidate our manufacturing processes, so we think it's the right and prudent step for us to take. This is a very painful process but it is what we believe is right for the business. Of the reductions we've made, we've basically done a force reduction from 72 people. Starting from about 240 of those people, 90% came from our manufacturing operation. I want to extend my personal thanks, and the thanks of the company, to these employees for departing. They have helped get us to the terrific position we are in today, and so while this is an extremely difficult time, this is the single reduction we're doing, and this process is now complete.

And so, I guess to sum up, prior to your questions, my view is that the job of the management of this company is to keep this company moving forward and to provide real leadership, communicating as openly as possible but also making the tough decisions that are really in the best interests of the shareholders. To carry that out, we've laid out a timeline which I hope is conservative, but it's one we will make. We've moved forward with personnel changes which we believe will help move this company forward faster in the future, and we've addressed structural cost issues which we've had actually for some time but simply should be addressed in the context of the time it'll take to make this response to the FDA. We're going to continue to do what we think is in the best interest of the shareholders and we hope our shareholders in turn will support us as we continue to be cautiously optimistic in moving towards both regulatory approval and an outstanding business in the future.

Those are my comments; I will now welcome any questions.

QUESTIONS AND ANSWERS

Operator

At this time, I would like to remind everyone that in order to ask a question, please press * then 1 on your telephone keypad. We'll pause for just a moment to compile the Q&A roster.

Your first question comes from Marcus Denennero (ph) , from Smith Barney.

Marcus Denennero - *Smith Barney - Analyst*

Yes, the question is: you have experience in South Africa with your products. What's been the result of that experience, and other international possibilities?

Thomas Moore - *CEO, President - Biopure Corporation*

Our stretch in South Africa has been very positive from the standpoint that we have had good experience with the patients and developed what we consider a very good safety record with the product. It has been approved for use in general surgery in South Africa, and so it's being used in a wide variety of situations. We've reported and carefully tracked the usage of this product, reported very good therapeutic results. In particular, in the past, we've talked about experience in areas like breast reconstruction surgery where practices have converted totally to the use of our product as opposed to transfused blood based on their perception that the product is providing superior healing rates, lower infection rates and less tissue rejection which is important particularly in the case of breast reconstruction surgery as that is generally followed by radiation or chemotherapy which can only be begun when healing is in fact complete. We continue to get very good interest in the product, we are continuing to opt the product on the interim free basis as we are restructuring our commercial agreements in South Africa so that we can in essence leave the partnerships that we've currently been in which has developed some real issues and market this with a new partner. That activity is going on now, but the record of the product and how it's been used is quite good.

Marcus Denennero - *Smith Barney - Analyst*

I'm sorry.

Thomas Moore - *CEO, President - Biopure Corporation*

Marcus (ph) had a second part of his question. He asked about other international work.

We have, sorry about that. We have had - we have had regulatory discussions both with the European central regulatory authorities as well as with specific European countries. We have prioritized, however, our response to U.S. FDA as our really top priority.

And while we're continuing to pursue these and there are certainly some very real interest in the product there, we are going to strategically hone our resources to make our FDA

response our top priority and any other international opportunities something we pursue a as the resources are available basis.

M a r c u s (ph) , does that answer your question?

Marcus Denennero - *Smith Barney - Analyst*

Yes, thank you.

I have another question if no one else is on the line.

Thomas Moore - *CEO, President - Biopure Corporation*

Well, there are about 151 others.

There are? OK.

Thomas Moore - *CEO, President - Biopure Corporation*

Why don't you fire away M a r c u s (ph) , and I'll try to be succinct.

Marcus Denennero - *Smith Barney - Analyst*

Yes.

Just quickly, is there a possibility of getting fast track on your products for compassionate uses?

Thomas Moore - *CEO, President - Biopure Corporation*

Those are two things, different things.

First off ...

Operator

Please hang up and try your call again. If you need assistance, dial ...

Thomas Moore - *CEO, President - Biopure Corporation*

Are we still online?

Operator

Yes.

Thomas Moore - *CEO, President - Biopure Corporation*

OK, good.

So in terms of fast track, we're past the point of fast track 'cause we're well down the regulatory consideration phase here. And so right now the FDA has been tremendously responsive to what we're trying to do. And I assume that will continue to be the case.

In terms of compassionate use, the company closed down its U.S. compassionate use program I guess about three years ago. The problem with compassionate use is it's a very uncontrolled way to use the product. And frankly by its very nature it tends not be as helpful as you'd like it.

Marcus Denennero - *Smith Barney - Analyst*

It's truly a last resort use of the product as opposed to a situation where a patient could really therapeutically benefit from it.

I will say I think as we look forward, we're probably going to re-review that issue. And see whether that isn't a smart thing to do.

However, any program we would do would have to be very carefully constructed because an open-ended compassionate use program ends up required enormous resources. So the company is we are responsible for how the product is used, the training of the medical personnel who use it, and inevitably as should be and as is appropriate, for the recording the ultimate medical outcome to our fundamentally medical file.

So M a r c u s (ph) , there is another short answer to your question.

Marcus Denennero - *Smith Barney - Analyst*

Thank you.

Thomas Moore - *CEO, President - Biopure Corporation*

But that is something we will look at again once we're confident we have - we are in very good shape on our BLA response.

Marcus Denennero - *Smith Barney - Analyst*

All right, thanks.

Operator

Your next question comes from Bruce Peterson (ph) with Janney Montgomery Scott.

Bruce Peterson - *Janney Montgomery Scott - Analyst*

What it's going to cost the company for this one time charge of eliminating one-third of the employees? And give us a feel on how the company is going to fund the timeframe going out to June of '04 and beyond?

Thank you.

Thomas Moore - *CEO, President - Biopure Corporation*

Sure.

The cost of the severance program will be the number that we have right is about $985,000. So I think it's fair to say about a million. That represents a little over 3% of the current cash resources we have on hand. With all that figured in, with cash on hand we're in a position where we could operate into the May/June timeframe.

We are in discussions right now setting up a financial facility which would allow us to raise the necessary resources to actually keep the company operating through the end of 2004. This is a so-called standby equity agreement - basically allows the company to sell shares as needed directly into the marketplace. We've used a standby equity facility already very successfully over the past year, and we believe that, assuming we can once again renew this facility and we don't think there's an issue to that, that we'll be able to, without doing a significant new offering, be able to operate through the end of 2004.

Bruce Peterson - *Janney Montgomery Scott - Analyst*

Thank you.

Thomas Moore - *CEO, President - Biopure Corporation*

You're welcome.

Operator

Your next question comes from Gudrim Bowler (ph), an investor.

Gudrim Bowler - - *Analyst*

Yes, I have a question regarding the sampling (ph) approach that will not guarantee to meet FDA requirements. I'd like to understand why now at the eleventh hour it's finally figured out that that approach won't work. Having listened to past speeches about how people had been hired as consultants and employees to "address the FDA needs and understand them," I'd like to know how in the eleventh hour it's finally figured out that you don't have even the approach that the FDA wants.

Thomas Moore - *CEO, President - Biopure Corporation*

I guess number one I think all along we knew that the sampling (ph) approach may or may not work. It seemed right to talk with FDA and we (ph) in fact set up the meeting with FDA within a couple hour - a couple weeks, rather, after receiving the letter. All along, we began our preparation to actually do the full source data collection, and in fact have kept going on that track even as we were having the discussions with FDA. And so I'm not sure it's eleventh hour because we've been working against this really since August.

Secondarily, I'd say while you characterized it as it's well known the FDA won't accept that approach, in point of fact the FDA has accepted that approach and several other regulatory filings that we uncovered (ph) in our research. And so it was not unreasonable to talk with FDA about the possibility of doing that.

And in point of fact, the FDA didn't say, "We won't accept it." They just said, "You know, guys, we can't tell you until you show us what you do whether or not it's going to work." And because the last thing I want to do is get into multiple cycles with FDA, we made the decision that we weren't going to put our shareholders at risk for having additional cycles with FDA because we didn't offer a complete enough answer to the FDA question.

So that's why we've gotten to this point. I know I can sense your irritation in your voice about - in the use of the phrase "eleventh hour," but it would be unfair to say that we just suddenly got surprised by this. We basically laid the groundwork

in place for full data collection starting off very early in the process. What we did do is we elected not to talk with our investors about what the schedule would be until we were sure we had exhausted the option of getting a shorter path.

Should I – is there any more you'd like me to convey?

Gudrim Bowler - - *Analyst*

I'd like to know why you're not further along in South Africa.

Thomas Moore - *CEO, President - Biopure Corporation*

There are fundamentally two issues. One is the company, frankly, did not do a full commercial introduction when the product initially became available there.

And then secondly, we took as our partner there a hospital chain, and as soon as we got into trying to start up commercial operations there, it became clear that structurally a hospital chain really isn't the right partner to have when you're marketing a pharmaceutical. Lack of – there's both issues concerning lack of experience in marketing pharmaceuticals as well as, frankly, competitive issues between hospital chains in South Africa which the management of the company simply was unable to anticipate.

So now we're unwinding that agreement so we can get into a more normal commercial kind of operation.

Gudrim Bowler - - *Analyst*

Thank you.

Thomas Moore - *CEO, President - Biopure Corporation*

You're welcome.

Operator

Your next question comes from Sapna Srivastava with ThinkEquity Partners.

Sapna Srivastava - *ThinkEquity Partners - Analyst*

Yes, hi, Tom. I have a few questions.

Thomas Moore - *CEO, President - Biopure Corporation*

Yes?

Sapna Srivastava - *ThinkEquity Partners - Analyst*

First of all, with the change in regulatory, I mean, who is going to be the person who is responsible for now c a r r y i n g (ph) the communications with the FDA? I mean it is a bit concerning to change at this point of the game. And how does the new person plan to get trained in the time, you know, which is pretty close? I mean even if it's a few months, it's pretty close to really understand the last, I don't know, 1 3 (ph) years of work or something. So a little bit of color on that would be very, very helpful. I would start with that and then I have a few more questions.

Thomas Moore - *CEO, President - Biopure Corporation*

Sure. David Zuchero will be our chief regulatory contact with FDA effective today. We have notified the agency of that change. Nevertheless, I will emphasize David is – brings an enormous wealth of experience and strategic perspective to us, but it is our aim to hire a new senior regulatory officer who will assume that communications responsibility as soon as we find the right sterling individual who'll take that role.

Sapna Srivastava - *ThinkEquity Partners - Analyst*

I mean just you know level will not have a regulatory person while the product is under review. I mean who in the company is going to be r e g u l a t o r y (ph) responsible for any questions that are coming from the FDA right now?

Thomas Moore - *CEO, President - Biopure Corporation*

Well, we actually do intend to work through David for right now. I mean we have a regulatory team of six individuals who handle our regulatory process, and so it's not like we have any sudden void in terms of regulatory relationships with FDA or regulatory history with FDA. And again, I would emphasize that Howard was not running the FDA response process. In point of fact, I'm running the FDA response process and coordinating the work amongst the teams. The communication we sent to FDA announcing – informing them of the change was a letter that I signed personally.

And so Howard's leaving does not affect our ability to make the response. In terms of the communications with FDA, as you

know, they - I mean they're fairly formalized interactions back and forth at this stage. They're not particularly intense at this point because we're busy getting them the answers. We've done all the clarification - with Howard's help all the clarification we need to know what we've got to do and to know the extent of rigor we have to apply to it.

And so from our perspective, Sapna, this is a - this is an opportune time to make a change at what is broadly perceived as a sensitive spot, but it will not represent a gap in terms of ability to keep track of the history or ability to be able to communicate effectively with FDA.

Sapna Srivastava - *ThinkEquity Partners - Analyst*

OK, and the second question is, you know, obviously your timelines have slightly extended from the last time you gave the update on what it would take to get the response to the FDA. I mean could you just give a little bit more color, like, you know, why the timeline extended and how many people are working on getting the answers? Could this timeline be accelerated if you had more people trying to get the answers information, et cetera?

Thomas Moore - *CEO, President - Biopure Corporation*

Sure. We actually - I mean we provided some guidance briefly right after we got the letter which in part was based on the assumption that we had all the source data the FDA will be looking for already in house. And that was literally within the first 24-48 hours after we got the letter.

As we got into what the FDA is really looking for, we realized we would have to go out to the sites in order to collect that information and that's when we - when we provided the guidance at our Q3 conference call which said, "Gee, we need to have a meeting with FDA and we'll only know when exactly we're going to be able to set a timing commitment after we have those meetings with FDA." And so early on, we thought this would be easier because we had the data in house. It took literally a few days because you have to work with your contract research organizations and your data management organizations to find out exactly what you have. We discovered, "OK, this really is going to be a field trip."

How big a field trip will it be? Well, on the data gathering area alone, we have retained and trained 15 or so monitors to go out and actually collect the data. We've now contacted the vast majority of the sites and the - and they are - some are sending us the information directly. Others need to get visited by folks who know what to look for to be able to pull that information out. And so it represents a very substantial effort.

Once the material is in, we have to take the data out of the forms and tabularize it in the way the FDA has asked to see it tabularized to be able to do that. And of course, we have to do rechecking of it to make sure everything we send is accurate.

So it's a collection process which in our - in our timeline, at least, we're assuming is going to take several weeks. Then there's a data extraction process, which we can start almost right away when we get the source data in though it will still take some time to take it out. Then there's a checking and verification process and a tubularization process, and, frankly, we're also going to just make sure all of this reconciles well with everything we already have in house. And that's what pushes this timeline out.

Again, it's critically important for our investors that the timing promise we make is the one we meet, and that's what we're going to do. The issue here is probably while we could go from 15 monitors to 30 or 45 monitors, that only shortens up the collection process. There are several other steps we have to take. So if it were - frankly, if it were just the number of monitors, I would be - right after we finished this call, I'd have my ticket hopefully to Miami, but I fear that my staff would probably send me to Minneapolis instead, to actually pick up the data. But it's more to it than that.

Sapna Srivastava - *ThinkEquity Partners - Analyst*

And so how is that to extract the data from because obviously you're giving up control now for the data collection being having to actually go to the sites? I mean would that be a challenge? And I mean is that the only part of the questions which are still w h e r e (ph) you have to answer to the FDA or are there any questions on the efficacy and safety side which may be also more time consuming?

Thomas Moore - *CEO, President - Biopure Corporation*

In previous communications we've had, we've said there of the - all the questions we've gotten, there are about 50 which, you know, require some substantial effort on our part. None of those are going to be time-limited. We've focused on the source data collection because that's the one that takes all the time. The rest of them we're confident we can answer, and in fact, many of the answers have already been finished.

We for the sake of simplicity have focused on the source collection issues as being the one which will effect the issue investors are most concerned about, namely the timing of our response. But there are lots of other questions being answered. It's fair to say the majority - the vast majority of the non-manufacturing resources of the company are working on those questions. Though that'll start shifting over in the next few weeks as people complete the answers and can move back to other aspects of the business.

There was another aspect to your question. So far, and we're pretty far down the track, sites have been very cooperative with us in terms of getting this data back. There are both issues about their voluntary nature their cooperation. There've also been new confidentiality regulations and laws passed, notably HIPAA, since our trial began, which for some sites we thought could create a problem. And so, so far, I guess I'm pleased by what I see so far in site responsiveness. And if that continues to be very good, then I'm going to be even more comfortable about our June target date. But at this point - at this point, it's really so far, so good.

Sapna Srivastava - *ThinkEquity Partners - Analyst*

OK. And my last question - I apologize questions - but manufacturing, you've obviously, you know, reduced your manufacturing team by 90%. I mean assuming approval ...

Thomas Moore - *CEO, President - Biopure Corporation*

I'm sorry, Sapna, I miscommunicated then. I'm glad you said that. Ninety percent of the cuts come in manufacturing, but manufacturing force overall was reduced by I guess - I'd say it's about 40%.

Sapna Srivastava - *ThinkEquity Partners - Analyst*

OK.

Thomas Moore - *CEO, President - Biopure Corporation*

So it's a 40% manufacturing staff reduction, but they account for 90% of the individuals we've laid off.

Sapna Srivastava - *ThinkEquity Partners - Analyst*

So, but, I mean if you need to build it back towards the end of the next year, I mean, how much time would you need? And, like, also how does this impact South Carolina, you know, going forward manufacturing plant facilities?

Thomas Moore - *CEO, President - Biopure Corporation*

The way we structured it, and we made some very conscious choices on this because you can imagine there were alternate plans which have had a more dramatic effect on manufacturing, we structured it so that we would be able to build back quite rapidly. We have conscientiously retained the individuals with the highest degree of skill and experience in the organization.

And so we've done it in a way where we can really build back quite quickly and that was an important criteria laid out in the board (ph) when we (ph) did this. Again, this was all done not to hit a financial target but on a strategic way to say, "What capabilities are we going to retain? What are we going to give up?" And that's the way we've approached it.

And ...

Sapna Srivastava - *ThinkEquity Partners - Analyst*

South Carolina.

Thomas Moore - *CEO, President - Biopure Corporation*

... so we did that across the board both in the manufacturing as well as in our quality control and quality assurance sides where all the - all these organizations were left staffed in a way where we could staff up quickly.

In terms of Sumter, the Sumter Realty Group, which you know is the organization that's actually doing the financial negotiation with us, is engaged in active financial negotiations. We have instructed them to continue to do that. We have not moved away from the possibility of doing the Sumter agreement and hopefully they will have some news for us on that in the relatively near future, but that's not a negotiation we're engaging in directly ourselves.

Sapna Srivastava - *ThinkEquity Partners - Analyst*

But do you think your manufacturing plant will also be impacted by the same amount of delay, in terms of timeline?

Thomas Moore - *CEO, President - Biopure Corporation*

No, we don't think so. It'll take three years from the point where the shovel hits the ground to the point where the facility is up and running. And because our perspective on the approvability of the product is unchanged and because three years is a long, long time, we still think that it makes sense to move for them up-front.

Sapna Srivastava - *ThinkEquity Partners - Analyst*

And to the extent, Sumter, they're much like any other investors, the people that they're negotiating the financial agreement with. They want the questions answered; they want to understand the basis of what this call is. There might be a little shock at first, then maybe relief that we have a plan and a path moving forward, and then it's back to business. So that's the different perspective.

Thomas Moore - *CEO, President - Biopure Corporation*

Okay, thanks so much. I will say goodbye.

Unidentified Participant

Thanks Sapna.

Operator

Your next question comes from D a v e H o f f m a n (ph) with A c c e p i t o r (ph) Capital Management.

David Hoffman - *Accepitor Capital Management - analyst*

Hi, thank you very much for taking the question. I was just curious, what exactly was the day on which the head of regulatory R i c h m o n d (ph) left the company.

Thomas Moore - *CEO, President - Biopure Corporation*

As a matter of fact, it was late last week, and to be honest with you, I don't recall the exact day. It was late last week.

David Hoffman - *Accepitor Capital Management - analyst*

Okay, and just regarding the standby equity distribution agreement. Would that be similar to the Bank of New York agreement in structure?

Thomas Moore - *CEO, President - Biopure Corporation*

Yes.

David Hoffman - *Accepitor Capital Management - analyst*

Okay, so just to clarify, these are essentially purchasing stock from the company at a discount. So the market profit--

Thomas Moore - *CEO, President - Biopure Corporation*

Actually the way it works, it's the facility which allows the company to sell stock directly into the marketplace. There's a very small commission, it's 1% commission. So technically sir, you are right, it's a discount but it's only a discount of 1%. It's not anything beyond that.

David Hoffman - *Accepitor Capital Management - analyst*

So just one other question. Did the head of regulatory R i c h m o n d (ph) , was that departure, was he terminated or was that departure voluntary at this point?

Thomas Moore - *CEO, President - Biopure Corporation*

Well, Howard's a respected professional so I think the precise circumstances of hwo all this happened is sort of personal. I guess what I will say is that was something that was reached by mutual agreement. He did not choose to leave us, let's say.

David Hoffman - *Accepitor Capital Management - analyst*

Finally, if you could just give us a sense of what time any sort of charges might be taken with the workforce reduction? Assuming that happens by end of 2003, not including the standby facility, just what the end of 2003 cash balance might look like?

Thomas Moore - *CEO, President - Biopure Corporation*

I think my CFO won't let me give you the cash balance, but what we can say is... One, all the charges will be absorbed by

the end of 2003. And two, that with all those charges in, we'll still be a position with cash currently on hand to operate through probably through either late May or early June.

David Hoffman - *Accepitor Capital Management - analyst*

Right, and the facility would take you through the end of 2004?

Thomas Moore - *CEO, President - Biopure Corporation*

Exactly.

David Hoffman - *Accepitor Capital Management - analyst*

Great, well thank you very much. Best of luck.

Unidentified Participant

This is Douglas. I think we can take two more questions and then we have other obligations today. We can talk individually after that. For those of you on the call, you may want to make a note that our earnings call and press release are on the December 11th. We may have other things to say before that. But do more two more questions, and then we'll end this call.

Operator

Your next question comes from Jakar Boz (ph) with Greenberg Healthcare.

Jakar Boz - *Greenberg Healthcare - Analyst*

Hello, can you hear me?

Thomas Moore - *CEO, President - Biopure Corporation*

I can barely hear you but I'm listening as carefully as I can.

Jakar Boz - *Greenberg Healthcare - Analyst*

Okay. I just wondered if you could walk us through the timelines and milestones between now and June that would give the impression to the investors that these issues have been resolved with the FDA, and that the items that the FDA would like from you have been obtained by your research people adequately. Whether you meet those guidelines in line with what the FDA has requested. Between now and June is a big black box, I mean. Do you have any idea what's going to happen until June and until the FDA accepts it afterwards?

Thomas Moore - *CEO, President - Biopure Corporation*

I understand, and I'm quite sure that during this period, we'll be providing investors with regular updates of where we think we'll stand and how we're doing on this. The key issue is sort of as I described: the three phases of what we have to do with gathering the source information. First the gathering per se. And we've allowed ourselves between two and three months to complete the gathering process. And then data extraction and tabulation process, and then it's just finally summarization and the other kind of things we have to do with that. And so--

---

Jakar Boz - *Greenberg Healthcare - Analyst*

No, I'm not asking that part of the question, we can all collect data. But what I'm wondering is that the data and the collecting, to begin with, is the appropriate data? That the FDA will finally find it adequate and satisfactory?

Thomas Moore - *CEO, President - Biopure Corporation*

We know exactly what the FDA is looking for, and we're quite sure we can collect it. And from that standpoint, quite frankly, we don't have much concern about whether or not the principal work we're doing here is the right work to do. I think the more fundamental question that you are interested in as everyone is, is this answering all the FDA questions. Is this going to be everything the FDA could possibly want in order to move forward with an action letter? The FDA has used with us repeatedly the phrase that "This is the roadmap" for where we need to go to move forward, and we're taking them not just at their word but based on the repeated correspondence with them that that in fact is exactly what we're doing.

And so we will - we will, as we develop our lists, we'll also, we'll be working with FDA to make sure we are getting all the issues they have, even the ones they may not - that may not be in the letter. But at this point, what they said is hey, the letter is everything. Give us what we ask for and we'll be moving forward.

So that's what we're focused on. I appreciate, you know, it'd be great to have a lot of other little milestones but it really is got to answer all their questions and that what we're doing.

Jakar Boz - *Greenberg Healthcare - Analyst*

OK. So are they keep us in this change recently? Because his appreciation of what the FDA were different to what the FDA is willing to put on writing and other receipt in writing. Were you going to address the issues of the new regulatory person on board?

I'm not quite understanding why the change in management was made if we indeed have everything down right from the FDA already. I'm a little confused.

Thomas Moore - *CEO, President - Biopure Corporation*

There's absolutely no issue about his interpretation of what we have to do and the company's interpretation or for that matter FDA's interpretation.

It's really a very explicit roadmap.

The change there was done for issues, which are - the change there has nothing to do with the FDA response. It has more to do with where we feel we need to go as a company. And some of the other strategic issues we want to address and the kind of resources we want to bring in to expand the scope of what we're doing.

And this was an opportune time to make that change because we had just completed all the dialogue with FDA over clarification on alert. A dialogue, which was very productive, raised no new issues. Simply said, guys, sample in one field, at least our conclusion from it was that it was in the best interest of the shareholders not to take a sampling approach but to go out and get it all the data.

But I really do want to emphasize, 'cause your question is one I know that a lot have, is that this has nothing to do with the FDA response letter. And because H o w a r d (ph) was not managing the response process, it doesn't impact our ability to make that response happen in a timely fashion.

Jakar Boz - *Greenberg Healthcare - Analyst*

Thank you very much.

Thomas Moore - *CEO, President - Biopure Corporation*

You're welcome.

Unidentified Participant

OK. We can do one, maybe two. I know there's people at the top of the queue that have been waiting a long time.

If we can fit two in quickly, let's do that.

Operator

Your next question comes from K e v i n T a n g (ph) with T a n g C a p i t a l (ph) .

Kevin Tang - *Tang Capital - Analyst*

Thanks for taking my question.

I'm - can we discuss a little bit, you're going to go out in the field and gather the raw data, case report forms, et cetera. There hasn't been much discussion about, gee, what are you going to find in those data?

Presumably if you find something, presumably you're going out to look to gather that data for a reason. And the reason might be there may be potentially some discordance with the data you've presented to the FDA?

And if so, then would that then not trigger another trial requirement?

Thomas Moore - *CEO, President - Biopure Corporation*

I don't think it would trigger another trial requirement. Though I'm, when I last checked my business card I don't work for FDA. But we don't think it's going to show - we don't think it's going to show any difference in the data.

But if it were to do that then I suppose the one thing we'll do is kind of look and see if there is any difference, whether it's significant or not. We don't expect it will be.

Kevin Tang - *Tang Capital - Analyst*

OK. But if there was not a possibility then of course wouldn't be any need to go collect it, right?

I'm just trying to understand why would they have you go collect this data unless there was some suspicion that there might be a difference?

Thomas Moore - *CEO, President - Biopure Corporation*

I really can't speculate on why they'd ask us to do that. All I can say we know, we don't think there's any difference and I'm not sure that they think there is any difference. But they are asking us to do that.

Kevin Tang - *Tang Capital - Analyst*

OK. And then when you re-file, that triggers a six-month or a 12-monnth-review time?

Thomas Moore - *CEO, President - Biopure Corporation*

If the FDA chooses to classify this is a class two resubmission, and again I can't say what FDA would do, then that would be a six-month response time.

Kevin Tang - *Tang Capital - Analyst*

OK. And if they don't it would be how long?

Thomas Moore - *CEO, President - Biopure Corporation*

It would be less. You have your choice of six months or less.

Kevin Tang - *Tang Capital - Analyst*

OK. So there's no way it would be more than six months?

Thomas Moore - *CEO, President - Biopure Corporation*

Not under FDA regulations. But I will emphasize the FDA have lots of options to do what they feel they can do.

But under P e d u f a (ph) , at most it's six-month response time.

Kevin Tang - *Tang Capital - Analyst*

OK. OK. And then one last question and I - you probably discussed in the past. The delays of manufacturing facility build, obviously understandable given their capital requirements of that and so on, give what's going on.

But what would be your capacity to launch, what is your current manufacturing - what if your manufacturing capacity short of building a new plant I guess is what I'm asking?

Thomas Moore - *CEO, President - Biopure Corporation*

Sure. The current, the machines we currently have in place give us a capacity of about 75,000 units per year of Hemopure.

Kevin Tang - *Tang Capital - Analyst*

OK. And then ...

Thomas Moore - *CEO, President - Biopure Corporation*

Even though we're doing a staff reduction, OK? The staff in place will be continuing on projects that we have, we already have in process, which will allow us to ultimately increase the capacity to 95,000 or so units a year.

And while that process will go on a little slower, that process will continue going.

So our anticipation is upon approval we'll have capacity of 95,000 units a year. And we hope we will have our Sumter facility under construction so we will heading to add an incremental 500,000 units of capacity not too long after product launch.

Kevin Tang - *Tang Capital - Analyst*

OK. And that's, I should think about that as kind of a 30, 30 odd million-revenue capability at launch?

Thomas Moore - *CEO, President - Biopure Corporation*

I think it's higher than that. I think we would say it's closer to a $60-70 million revenue capability.

Kevin Tang - *Tang Capital - Analyst*

OK. All right. So we don't have to get in that now, but that's assuming something like a 200% premium to blood costs?

Thomas Moore - *CEO, President - Biopure Corporation*

We could have a very interesting discussion on what blood really costs, in our view that would represent roughly a 30-40% premium only.

Kevin Tang - *Tang Capital - Analyst*

OK. And the one last question and I'm needing the story, but I'm just trying to dot all the i's here.

Is there any litigation risk in the, any litigation undergoing that you can update us on, if there are and if not, great?

Thomas Moore - *CEO, President - Biopure Corporation*

There's, well there's only, there's one litigation going on and that relates to - I'm getting a little advice here on how to exactly how to go. It's a contractual issue, it's a contract case that's being litigated. It has nothing to do with the conduct of the business.

So to give you a straightforward answer to your question is there's one piece of litigation currently going on. And it is in our 10-Q.

Kevin Tang - *Tang Capital - Analyst*

OK.

Thomas Moore - *CEO, President - Biopure Corporation*

So beyond that there is no other new litigation activity going on.

Kevin Tang - *Tang Capital - Analyst*

And just the timeline of that? Is it resolving in this next year or ...

Thomas Moore - *CEO, President - Biopure Corporation*

Oh, yes. Yes, this is - this is one, well I won't characterize the case. All I'll say is it's not too complex and so I think ultimately it's going to be - it's going to rest on the parties deciding what they really want to do to get this out of the way.

Kevin Tang - *Tang Capital - Analyst*

And have you factored that into your cash lasting 'til the end of '04 scenario?

Thomas Moore - *CEO, President - Biopure Corporation*

We really can't predict what'll happen with that. And so the answer is we haven't - we haven't put in a particular figure on that but at the same time we don't think it's appropriate.

So that's really all I can say about it at this point.

Kevin Tang - *Tang Capital - Analyst*

OK. All right. Thank you.

Thomas Moore - *CEO, President - Biopure Corporation*

You're welcome.

Thomas Moore - *CEO, President - Biopure Corporation*

OK. Let's do one last call and then we're going to have to move on. We have other obligations that are about to start. So that'll be it. One more please.

Operator

Your final question comes from S t e v e n M a r k s (ph) with Blue Ridge Capital.

Thomas Moore - *CEO, President - Biopure Corporation*

Hi, S t e v e n (ph) .

Steven Marks - *Blue Ridge Capital - Analyst*

How are you doing?

Hey, just so I understand a little bit better, you made the point a couple of times that how, I was just more interested in how was the SVT of regulatory affairs not managing the process with the FDA?

Thomas Moore - *CEO, President - Biopure Corporation*

I don't think he said he wasn't managing the process.

Steven Marks - *Blue Ridge Capital - Analyst*

OK.

Thomas Moore - *CEO, President - Biopure Corporation*

He certainly was the managing the process of the FDA. What I said is he's not managing our response, OK? Because the response represents the work of a lot of people ranging from our clinical folks who are out collecting this data and arraying it and the statisticians who work with it. Our medical personnel who are dealing with medical interpretation discussions and the like, our manufacturing people, while we've got very few manufacturing questions there were a few. Even our current management people are answering candid, intimate questions about cows, OK?

So this is not the answer in its final form will pass through regulatory because regulatory will ultimately say yes this is the right format, the right way to answer this question and assist then with our total regulatory strategy. And so from that standpoint, you need regulatory leadership.

But frankly, this is a project that requires good project management and management from me because the answer into these questions requires allocation of company resources and making sure everyone's making this job one.

And so Howard was not managing that total process. He was working with me on it. He was working with an in-house project manager we have to do that.

But the preparation of these answers goes well beyond simple regulatory expertise. There was expertise from all over the company being employed. And it's a key task we have as a company today.

So I've got to be on top of that.

Steven Marks - *Blue Ridge Capital - Analyst*

But he was managing the intimate process with the FDA, I take it?

Thomas Moore - *CEO, President - Biopure Corporation*

Yes. But it's not very intimate at this point because we had the discussions and the clarifications. The intimacy of the process right now is here's the list of questions it's, you know, hammered, nailed to the door like Martin Luther's principles and now we're going to answer them.

So it's not a nuance situation with FDA at this point. It's really a delivery thing.

I mean we've already answered many of the questions. We've got many more to finish up and that's - and that's a general management process. It's not an FDA relationship thing 'cause we're going to send FDA all the answers in one load.

Steven Marks - *Blue Ridge Capital - Analyst*

OK. And a couple more questions, you guys have said that the, there are kind of 50 substantive questions. How long was the letter that the FDA sent you guys?

Thomas Moore - *CEO, President - Biopure Corporation*

That actually was about 35 pages.

Steven Marks - *Blue Ridge Capital - Analyst*

OK.

Thomas Moore - *CEO, President - Biopure Corporation*

Which is typical in its breadth and content for a major new product application.

Steven Marks - *Blue Ridge Capital - Analyst*

OK, and then on South Africa, how many or two questions there. You guys said that the partnership has real issues. I just wanted to delve down and to understand what some of those issues were.

And then the second part of the question was how many units of the original, I think it was one to 2,000 units that you all shipped over, still remain to be used?

Thomas Moore - *CEO, President - Biopure Corporation*

Sure. I'll put it in graphic terms as a businessperson, S t e v e n (ph) you can appreciate.

Imagine my reaction when my South African team says we just paid a call on the number-two hospital chain in the private sector in South Africa and they said quote, "So long as you have this partner, we'll never buy a unit from you guys."

And the third biggest chain said the same thing.

And in fact they said basically none of us are going to buy a unit from you guys so long as you guys have this particular chain as your partner. I think you'll agree this is a major commercial issue.

And that's the one we're faced with.

Steven Marks - *Blue Ridge Capital - Analyst*

OK.

But let's say how into rolled were they in getting the product approved? I take it from my recollection they and then the, I can't remember what they were called, the - there's another group that sounded like they were pretty integral in getting the process approved.

Thomas Moore - *CEO, President - Biopure Corporation*

That actually isn't the case. Let me say one thing about my earlier little anecdote. I tell you this story but I want to make it clear it is the competitive reality how business appears to be done in South Africa.

It doesn't necessarily reflect badly on our partner as a company. It's just the way it is.

So having given you that small disclaimer, S t e v e n (ph) your question was, I apologize. Could you repeat your question?

Steven Marks - *Blue Ridge Capital - Analyst*

I'm trying to understand how integral they, and there was a, there was like a ...

Thomas Moore - *CEO, President - Biopure Corporation*

Actually we had for all intents and purposes, it appeared we had, as I've been told. I was not here on that happen, that we basically had the approval in hand when we in fact formed this partnership.

We in fact initially made the filing with another company there called MC Pharma.

Steven Marks - *Blue Ridge Capital - Analyst*

Yes.

Thomas Moore - *CEO, President - Biopure Corporation*

The filing was done with MC Pharma, not with this partner. So this partner is really with us on the commercial end. It was not with us with the filing at the regulatory end.

Steven Marks - *Blue Ridge Capital - Analyst*

OK, and then the number of units that still remain in South Africa?

Thomas Moore - *CEO, President - Biopure Corporation*

Approximately 850.

Steven Marks - *Blue Ridge Capital - Analyst*

And what the original, 1,000 or 2,000?

Thomas Moore - *CEO, President - Biopure Corporation*

Two thousand.

Steven Marks - *Blue Ridge Capital - Analyst*

OK. And then one last question for you, when you all initially announced the FDA letter, you all said that the clock was stopped and the FDA and you thought the FDA would respond within a month.

And now that doesn't seem to be the case. I'm just trying to understand what happened there.

Thomas Moore - *CEO, President - Biopure Corporation*

You're right, S t e v e n (ph) . I think - I think, we questioned that closely when it occurred and we termed the letter as a hybrid because it was, the language, frankly, was a little confusing to us in terms of where all that stacked up.

And because they were early in responding and because they used the phrase we have stopped the clock, our interpretation of that was when you stop the clock it means the clock gets restarted.

I think now as we look at the, actually the phrase they used was we suspended the clock. And so when you suspend something that means you can restart it again.

As we get into how, into however the depth of the response we got to provide and continue to have interactions with the agency, I think it's fair to say that when we respond, they'll restart the clock. But the clock probably won't have 30 days on it. And frankly it'd be unreasonable to expect it could 'cause this response is not going to be a five-page letter with a one-page cover note.

It's going to be much more comprehensive than that.

So I think it's fair to say that in the first couple of days of August when we were trying to communicate this immediately and quickly as possible, the ambiguity of the letter led us to serve an ambiguous outlook on what it really meant.

So we tried to clarify that since.

Steven Marks - *Blue Ridge Capital - Analyst*

OK. Thanks for the help.

Thomas Moore - *CEO, President - Biopure Corporation*

Thank you, S t e v e n (ph) .

OK. So we'd like to thank everyone for joining us today. And we look forward to talking to you soon.

Thomas Moore - *CEO, President - Biopure Corporation*

Thank you all very much.

Operator

Thank you for participating in today's teleconference. You may now disconnect.